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(54) **Introducer sheath.**

(57) A flexible, kink-resistant, introducer sheath for percutaneous vascular access. The introducer sheath includes a flat wire coil with uniform spacing between the turns, which is compression fitted about an inner, lubricous material polytetrafluoroethylene tube. The introducer sheath further includes an outer tube of a heat formable polyamide material which is heat formed and compressed through the spaces between the turns of the wire coil to mechanically connect to the roughened outer surface of the inner tube. The distal end of the outer tube is tapered in a mold with additional polyamide outer tube material. The proximal end of the sheath is flared for connection to a connector fitting. In the preferred embodiment shown in Fig. 8, the flat wire coil has an inner diameter less than the outer diameter of the inner tube, and the coil is expanded as it is unwound from the coil and wrapped around the inner tube to form a compression fit.

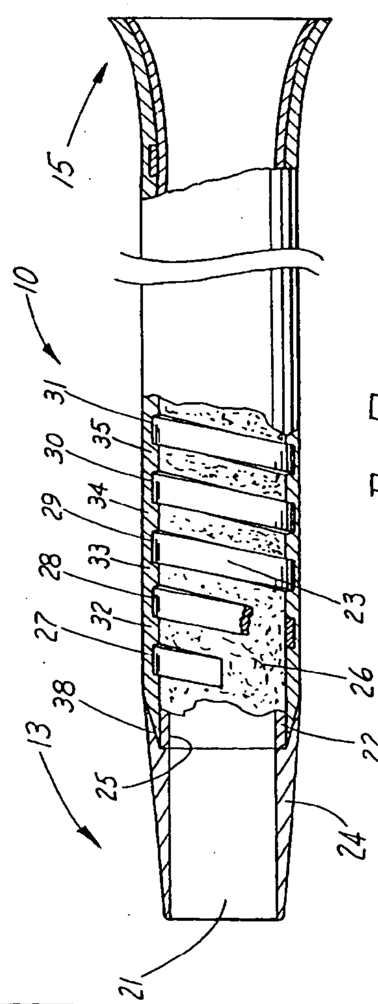

FIG. 2

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This invention relates to introducer sheaths.

Introducer sheaths are well-known for percutaneous vascular access and typically comprise polytetrafluoroethylene or fluorinated ethylene propylene. These sheaths are of a thin-wall construction, but tend to kink. Increasing the thickness of the sheath wall minimally improves the level of kink resistance, which is still unacceptable. Sheaths used in hemofiltration and dialysis, in particular, are prone to kinking since they remain positioned in a patient's body for a long time. While positioned in a patient, the sheath may be bent or pinched off and, as a result, kink due to repeated use or patient movement. A kinked sheath is unusable and cannot be straightened while positioned in the body of a patient. Consequently, the sheath must be removed, leaving an enlarged, bleeding opening, which typically cannot be reused. Vascular access is then attempted at an alternative site, and the procedure is restarted. Restarting the procedure causes a time delay, which may be life threatening. In some cases, an alternative site is not available for introducing another sheath.

Another problem with thin-wall sheaths is that an emergency room physician will typically kink an introducer sheath while inserting various catheters therethrough during emergency procedures. Small diameter introducer sheaths are also typically bent and kinked under the time constraints of an emergency situation. As a result, a new sheath must be introduced at the same or another access site.

Examples of introducer sheaths are described in U.S. Patent Nos. 4,634,432; 4,657,772; 4,705,511, and U.S. Application No. 07/741,689 filed 7th August 1991. These sheaths tend to have walls about twice as thick as those of PTFE sheaths for the same internal diameters.

According to the present invention, there is provided an introducer sheath as defined in claim 1.

The winding of the compression fitted coil on to the inner tube reinforces the wall to provide an extremely kink-resistant and thin-walled introducer sheath. A predetermined uniform spacing between the coils is achieved, and the inner surface of the inner tube is surprisingly smooth with obvious advantages. Extremely wide spacing weakens the wall and creates a rough inner surface. Narrow spacing does not allow sufficient room for connecting the outer tube to the inner tube.

In the preferred embodiment of the present invention, the turns of a coil having an inner diameter smaller than the outer diameter of the inner tube are unwound therefrom and are wound and compression fitted around the said inner tube. The turns of the first mentioned coil are thus pre-stressed, are consequently compression fitted on to the said inner tube. This advantageously eliminates the step of having to collapse the inner tube in order to insert it into the passage of the flat wire coil. This also advantageously significantly reduces the formation of any wrinkles in the inner tube such as would have occurred when the collapsed inner tube was expanded to form a compression fit against the flat wire coil described in EP-A-92306912.4.

A radiopaque marker is positioned adjacent the distal end of the coil to improve visualization of the sheath when inserted in a patient.

The method of manufacturing a flexible, kink-resistant, introducer sheath includes expanding the flat wire coil with a inner diameter less than the outer diameter of the inner tube and wrapping the coil when expanded around the inner tube. The outer tube is then longitudinally positioned around the inner tube and flat wire coil and connected to the inner tube through spaces between the turns of the coil.

Brief Description of the Drawing

FIGS. 1, 2, 3 and 4 are the same as Figs 1, 2, 3 and 4 described in European Patent Application 92306912.4 (Parker 3);

FIG. 5 depicts a partially sectioned view of the preferred embodiment of the present invention;

FIG. 6 depicts a side view of a coil transfer mechanism for winding and compression fitting a coil around an inner tube of the sheath of FIG. 5;

FIG. 7 depicts a top view of the coil transfer mechanism of FIG. 6; and

FIG. 8 depicts an enlarged view of a portion of the coil transfer mechanism of FIG. 7.

Depicted in FIG. 5 is a partially sectioned view of introducer sheath 40, which includes coaxial inner tube 42, flat wire coil 43, and outer tube 44 with tapered distal end 57 and flared proximal end 58. The connector valve 14 as shown in Fig. 1 can be inserted into flared proximal end 58 of the sheath for preventing the backflow of fluids therethrough. The sheath is formed by first winding and compression fitting flat wire coil 43 around inner tube 42 and then heat shrinking and mechanically connecting outer tube 44 to roughened outer surface 46 of the inner tube through the spaces between the coil turns. Radiopaque marker sleeve 72 is positioned adjacent to or distally of the distal end of the flat wire coil between the inner and outer tubes near the distal end of the sheath. Unlike flat wire coil 23 of sheath 10 in FIG. 2, flat wire coil 43 of FIG. 5 is wound around inner tube 42 to form the compression fit between the inner tube and wire coil. The coil is wound around the inner tube by expanding and wrapping the coil around the inner tube using, for example, a commercially available lathe and a transfer mechanism attached to the carriage of the lathe, which will be described hereinafter. This winding technique improves the manufacturing process and maintains closer tolerances for the uniform spacing between the turns of the coil. In addition, the inner tube is not compressed or collapsed for

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insertion into the passage of the flat wire coil. This advantageously eliminates any wrinkles in the inner tube wall and maintains closer manufacturing tolerances.

By way of example, kink-resistant, introducer sheath 40 is a 9.6 French (.126") sheath for inserting a 9.6 French dilator therethrough. Inner tube 42 is a 31 cm length tube of a lubricous material such as polytetrafluoroethylene having a uniform inside diameter in the range of 0.322 to 0.326 cms (.1267" to .1282") with a wall thickness of 0.005 ± 0.0025 cms (.002" ± .001"). The inner tube has a minimum inside diameter of 0.32 cms (.126"). The lubricous polytetrafluoroethylene material presents a slippery inner surface 45 for easily inserting and withdrawing a dilator as well as other catheters and medical apparatus therethrough. Inner surface 45 is also smooth and nonporous for minimizing the formation of blood clots and other thrombi thereon. Outer surface 46 of the inner tube is chemically etched to form a rough outer surface to which outer tube 44 is mechanically connected using the heat shrinking process described in connection with Figs. 104.

Coil 43 comprises a plurality of flat wire turns, for example, 47-51 with uniform spacing including equal width spaces 52-55 therebetween. Coil 43 is 30 cm in length with an outside diameter of 0.2 cms ± 0.0127 cms (.080" ± .005") prior to annealing. The coil is annealed by baking the coil at 800°F ± 25°F for approximately ten minutes. After annealing, the outside of the coil has a nominal dimension of 0.216 cms (.085"). The coil is formed from 0.01 cms (.004") thick by 0.03 cms (.012") wide flat rectangular stainless steel wire wound with a uniform space in the range of 0.013 cms to 0.0254 cms (.005" to .010") between the turns of the coil. Prior to being wound around inner tube 42, wire coil 43 has an inside diameter which is at least 0.1 cms (.040") smaller than the outside diameter of the inner tube. Wire coil 43 is wound and compression fitted around outer surface 46 of inner tube 42 approximately 3-4 mm from the distal end thereof and approximately 5 mm from the proximal end thereof to taper and flare the distal and proximal ends, respectively. After being wound around the outer surface of the inner tube, the spacing between the turns of the coil is approximately 0.018 to 0.023 cm (.007" to .009"). The coil is wound and compression fitted around inner tube 42 by inserting a mandril having, for example, an outside diameter of 0.32 cms (.1260") + 0.0005 cms + (.0002") -.0000" through passage 41 of the inner tube and positioning the mandril and tube into the head and tail stock of a commercially available lathe such as the Grizzly Model No. G-1550. A transfer mechanism, as depicted in Figs. 6-8, is mounted on the carriage of the lathe to wind and compression fit the coil around the inner tube.

Outer tube 44 is 31 cm in length with a preshrunk inside diameter of 0.368 ± 0.005 cms (.145" ± .002") and consists of a heat formable polyamide material such as radiopaque nylon that is heat shrunk over coil 43. The outer tube has a nominal preshrunk outside diameter of 0.4 cms (.158"). The wall thickness of the nylon tube is approximately 0.0165 ± 0.00254 cms (.0065" ± .001"). After the outer tube is heat shrunk and mechanically connected to the inner tube through the turns of the flat wire coil, sheath 40 has a overall nominal wall thickness of 0.0279 cms (.011") with an outside diameter of 0.378 ± 0.005 cms (.149" ± .002"). Tapered distal end 57 of the sheath is formed by grinding externally tapered surface 56 on the distal end of outer tube 44 for a distance of approximately 2 mm from the distal end of radiopaque marker 55. The flared proximal end extends for approximately 5 mm from the proximal end of flat wire coil 43 and is formed using a well-known flaring tool with heat applied to the proximal ends of the tubes.

Prior to heat shrinking the outer tube to the inner tube, radiopaque marker 72 is inserted over the distal end of the inner tube next to flat wire coil 43. Radiopaque marker 72 is approximately 0.127 ± 0.0127 cms (.050" ± .005") long with an outside diameter of 0.353 ± 0.00127 cms (.139" ± .0005") and an inside diameter of 0.34 ± 0,00127 cms (.134" ± .0005"). The marker comprises, for example, 10 percent iridium with the remainder being a platinum material.

Depicted in FIG. 6 is a side view of coil transfer mechanism 59 mounted on carriage 60 of a commercially available lathe such as the previously identified Grizzly Model No. G-1550. This side view is viewed from the tail stock end of the lathe. The coil transfer mechanism includes adapter plate 61, which is horizontally mounted on the carriage of the lathe, and tool holder 62, which is vertically mounted on the horizontal adapter plate. Pivotedly mounted on the tool holder is adjustable guide support 63 with semicircular recess 64 extending through the guide support adjacent the free end thereof. Extending perpendicularly from the guide support toward the tail stock of the lathe is coil retaining pin 65. The coil retaining pin engages the flat wire coil to unwrap the coil while the lathe rotates a mandril with the inner tube mounted thereon. While the mandril and inner tube are being rotated the expanded coil is being wrapped and compression fitted on the outer surface of the inner tube. The transfer mechanism also includes adjustable shield 66 which is positioned adjacent the rotating inner tube to prevent the flat wire coil, which is being unwrapped, from scoring the surface of the inner tube.

Depicted in FIG. 7 is a top view of coil transfer mechanism 59 mounted on lathe carriage 60. Also depicted is head stock 67 and tail stock 68 of the lathe with mandril 69 and inner tube 42 rotatably mounted therebetween. Adjustable guide support 63 has been positioned to cradle mandril 69 and inner tube 42 in recess 64 of the support. Coil retaining pin 65 faces toward tail stock 68 and is adjacent to the rotating

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mandril and inner tube. The longitudinal axis of the retaining pin and mandril are substantially parallel to one another. Adjustable shield 66 is depicted in a raised position in order to mount the mandril and inner tube between the tail and head stocks. As flat wire coil 43 is wound around inner tube 42, the coil transfer mechanism and the carriage of the lathe move relative to the head and tail stocks as indicated by arrow 70.

FIG. 8 depicts an enlarged view of adjustable guide support 63 and adjustable shield 66 of FIG. 7 with inner tube 42 and mandril 69 positioned therebetween in recess 64 of the support. To start the coil winding process, several turns of coil 43 are manually wrapped around the distal end of inner tube 42 mounted on mandril 69. The next several turns of the wire coil are positioned over coil retaining pin 65, as depicted. Adjustable shield 66 is then slid down and adjacent the inner tube to prevent the remaining free end of the coil from scoring the surface of the rotating inner tube. The lathe is turned on and rotated in the direction of arrow 71 to expand the coil with retaining pin 65 and wrap the coil turns around the outer surface of the rotating inner tube. The coil transfer mechanism moves as indicated by arrow 70 at a speed controlled by the lathe carriage to control the spacing between the coil turns. A uniform spacing between the coil turns of 0.018 to 0.023 cms (.007" to .009") is easily maintained using this coil winding procedure. After the desired length of coil is wrapped around the inner tube, the mandril, inner tube and wrapped wire coil are removed from the lathe. The outer radiopaque marker 72 is positioned adjacent the distal end of the coil, and outer tube 55 with a shrink wrap tube positioned thereover is coaxially positioned over the wrapped wire coil and inner tube. The outer tube is then heat shrunk and mechanically connected to the inner tube through the turns of the flat wire coil as previously described with respect to the procedure detailed in FIGs. 3 and 4.

It is to be understood that the above-described flexible, kink-resistant, introducer sheath is merely an illustrative embodiment of the principles of this invention and that other introducer sheaths may be devised by those skilled in the art. It is contemplated that various other materials may be utilized for the inner, outer, and heat shrink tubes. It is also contemplated that introducer sheaths with an inside diameter ranging in size from 5.5 to 14.0 French are readily producible. In summary, the flexible, kink-resistant, introducer sheath provides a thin-wall sheath that is extremely kink-resistant for long-term use applications. The flat wire coil construction of this introducer sheath is also extremely kink-resistant with small outside diameter dilators during introduction through an access site.

Claims

1. A flexible, kink-resistant, introducer sheath (10), comprising

   an inner tube (22) having a passageway extending longitudinally therethrough: CHARACTERISED BY

   a coil (23) having a plurality of turns (27 to 31) positioned longitudinally and compression fitted around said inner tube, said turns having been compression fitted about the inner tube by winding the turns of a coil around the said inner tube; and

   an outer tube (12) positioned longitudinally around said coil and said inner tube and contacting said inner tube through the spaces (32 to 55) between said turns.

2. The sheath of claim 1, wherein the passageway of the inner tube is of uniform diameter.

3. The sheath of claim 2 wherein said inner tube comprises a lubricous material, such as polytetrafluoroethylene.

4. The sheath of claim 1, 2 or 3, wherein said outer tube comprises a polyamide, such as nylon, and/or the inner tube includes a roughened outer surface.

5. The sheath of claim 1 wherein each of said inner and outer tubes extends beyond the end of said coil, the end of said outer tube optionally ending beyond the end of said inner tube and being tapered.

6. The sheath of claim 5 further comprising tip material bonded to the distal end of said outer tube, the ends of said inner and outer tubes optionally being flared.

7. The sheath of any one preceding claim, further comprising a radiopaque marker positioned about a distal end of said coil.

8. The method of manufacturing a flexible, kink-resistant, introducer sheath comprising the steps of:

   providing an inner tube having an outer diameter and a passageway extending longitudinally therethrough;

   providing a coil having a plurality of turns and an inner diameter less than said outer diameter of said inner tube;

   providing an outer tube;

   winding said coil around said inner tube;

   longitudinally positioning said outer tube around said coil and said inner tube; and

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connecting said outer tube to said inner tube through spaces between said turns.

9. The method of claim 8, wherein the step of connecting said outer tube to said inner tube includes positioning a heat-shrink tube around said outer tube and heating said heat-shrink tube to compress said outer tube through said spaces between said turns.

10. The method of claim 8, wherein the step of winding said coil around said inner tube includes rotating said inner tube, expanding said coil, and wrapping said coil when expanded around said inner tube.

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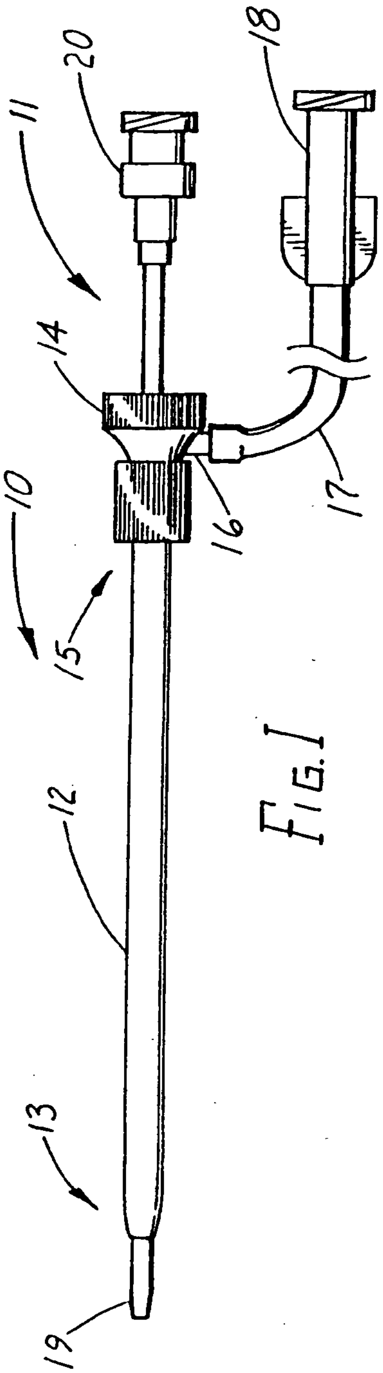

FIG. 1

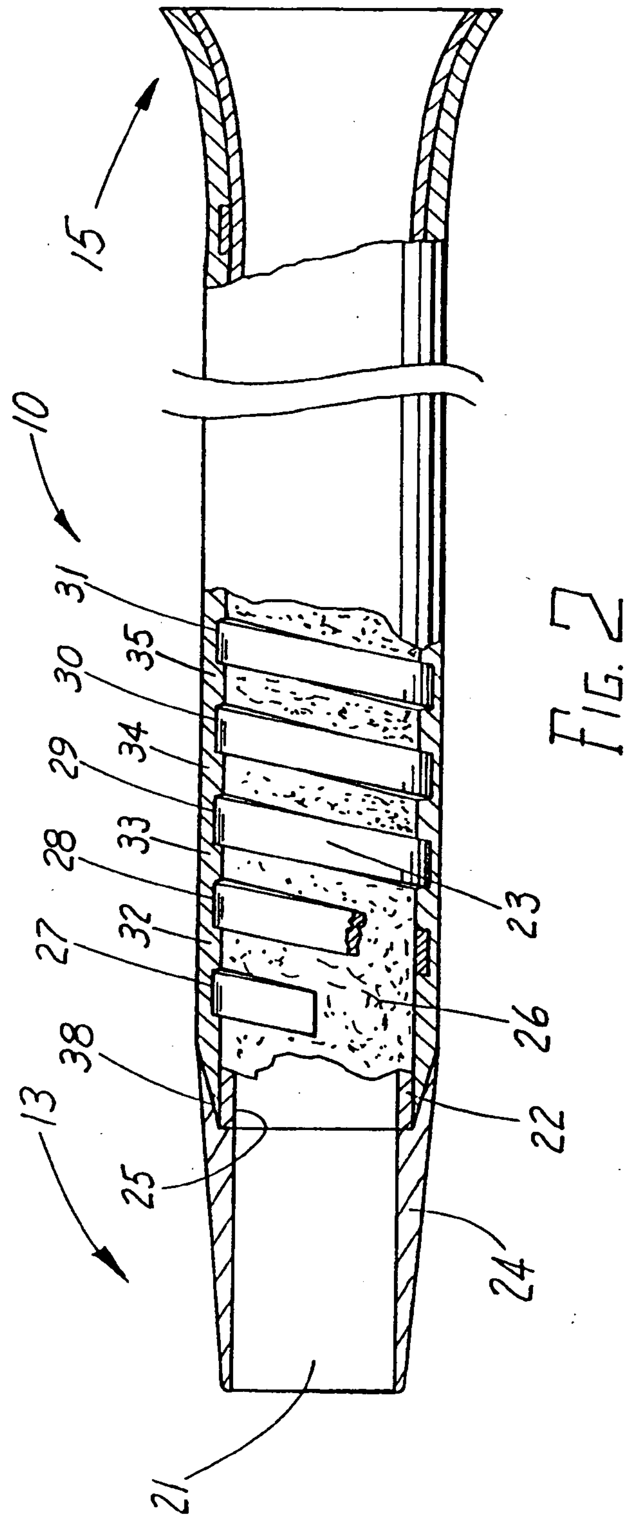

FIG. 2

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FIG. 3

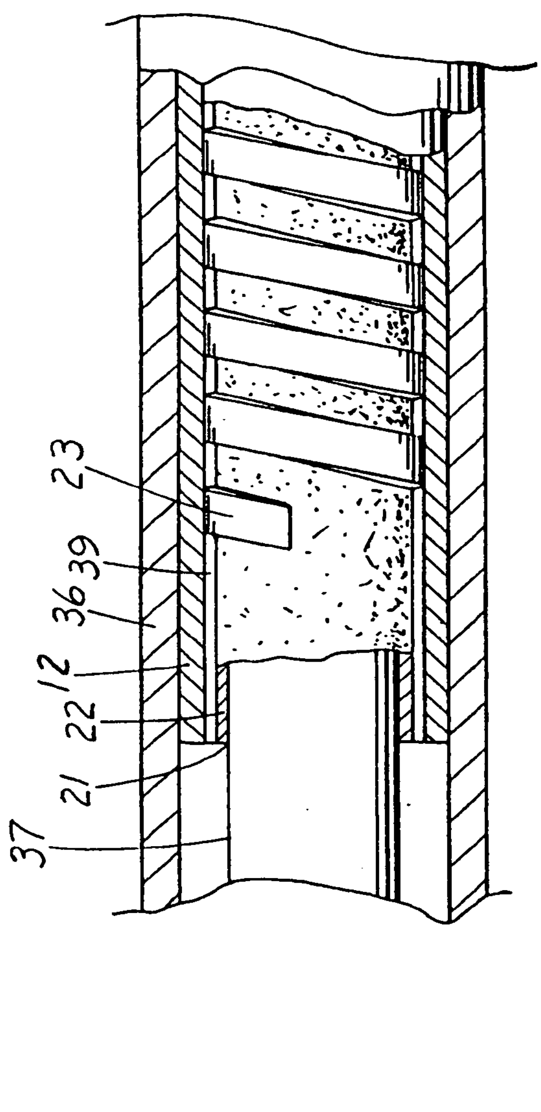
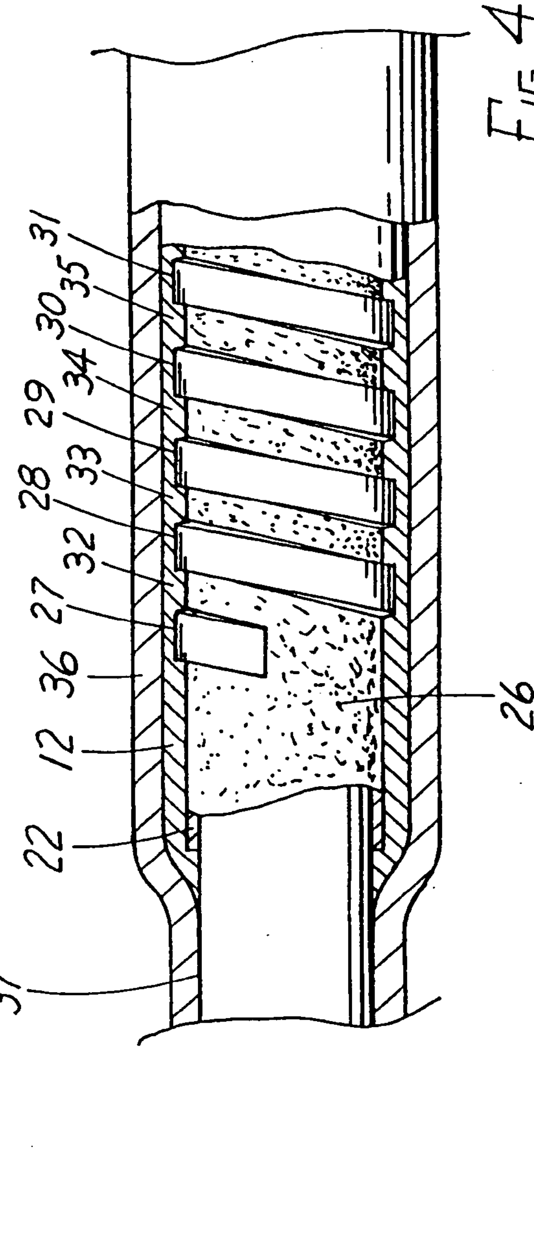


FIG. 4



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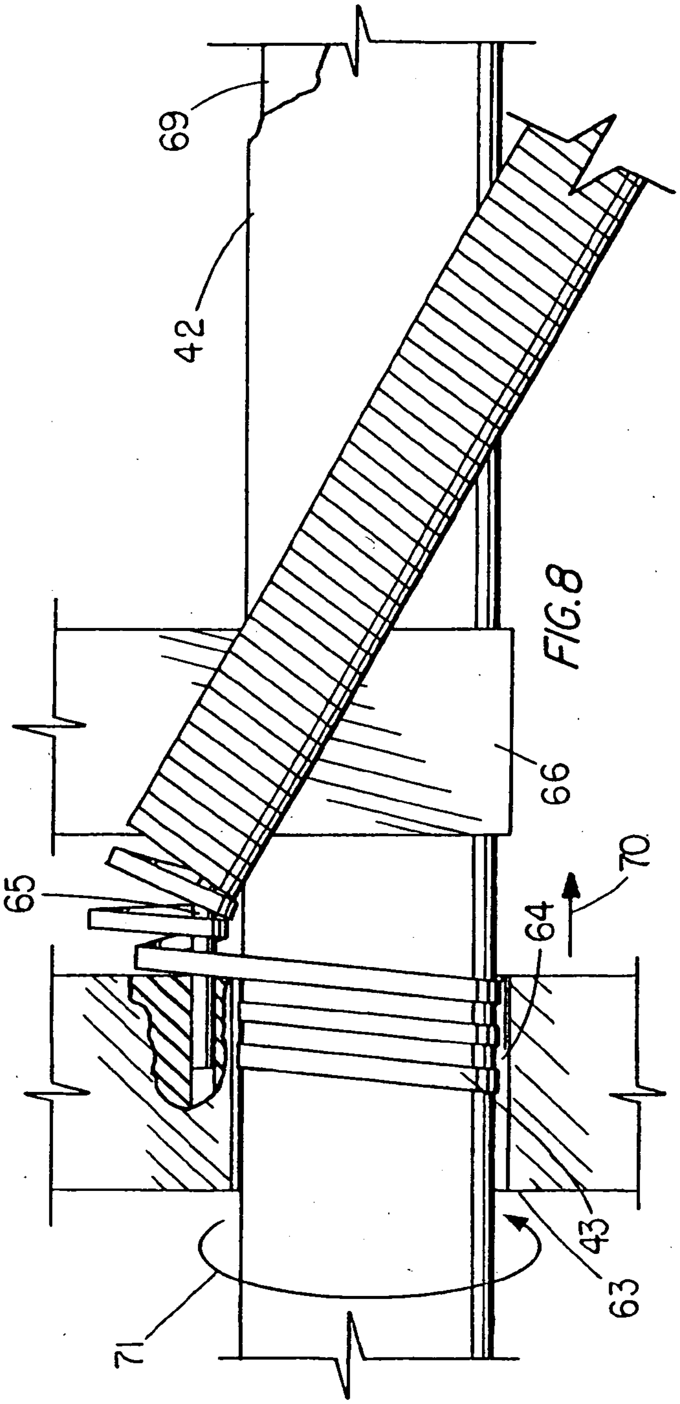
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FIG.8

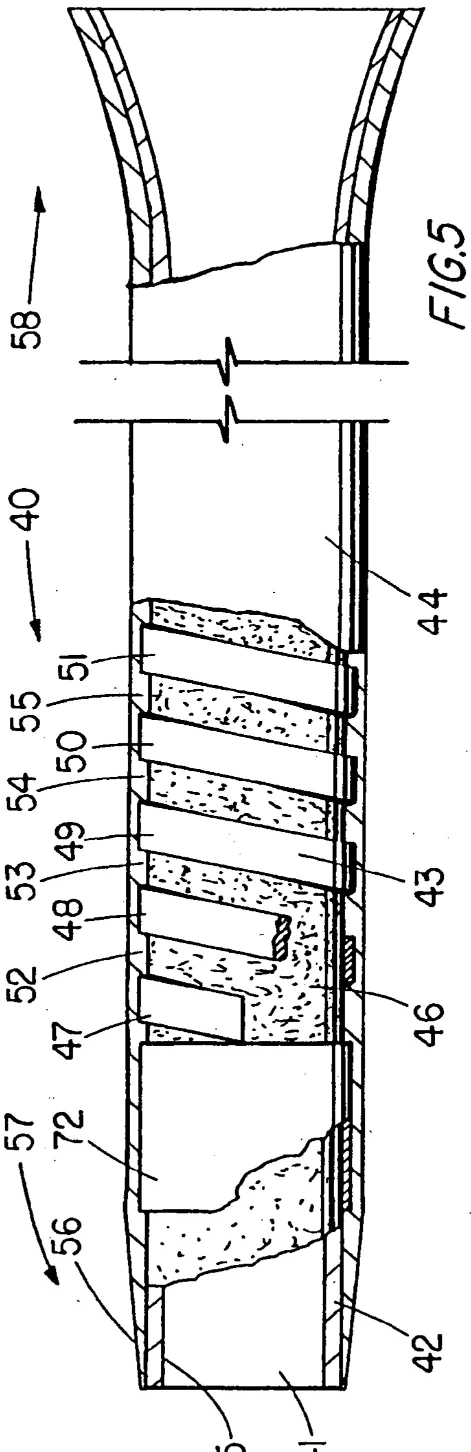
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FIG.5

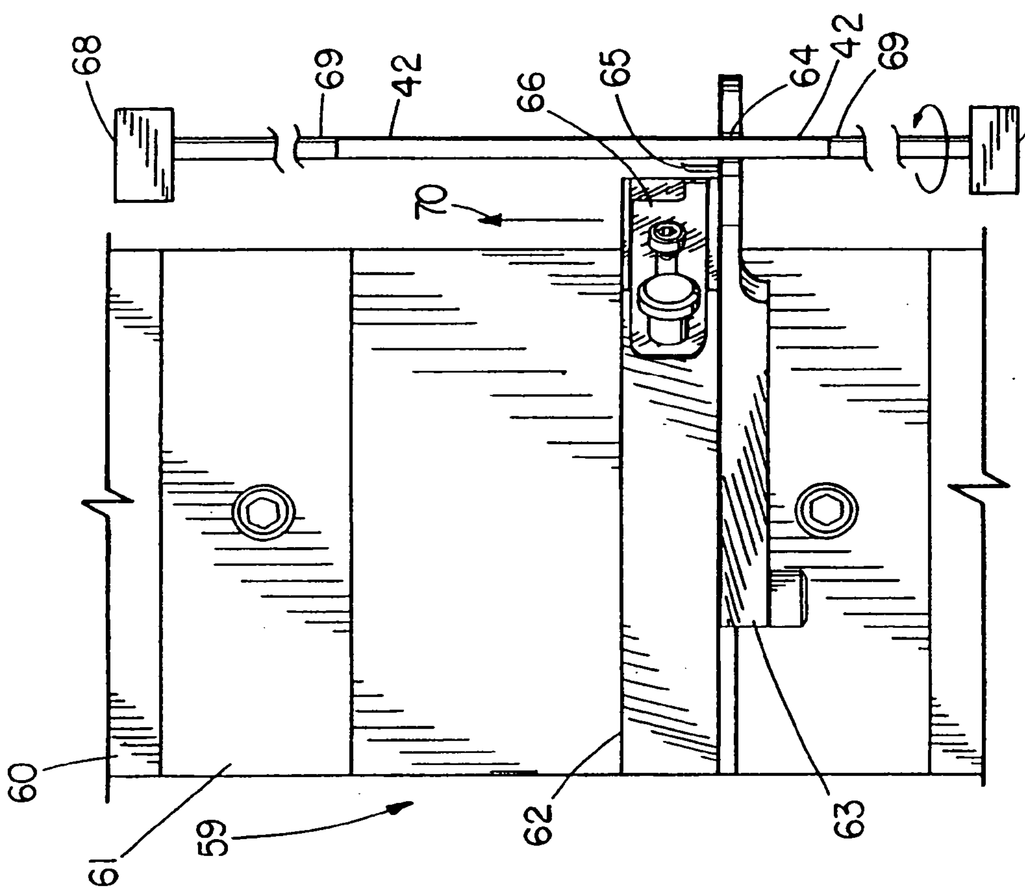

FIG.7

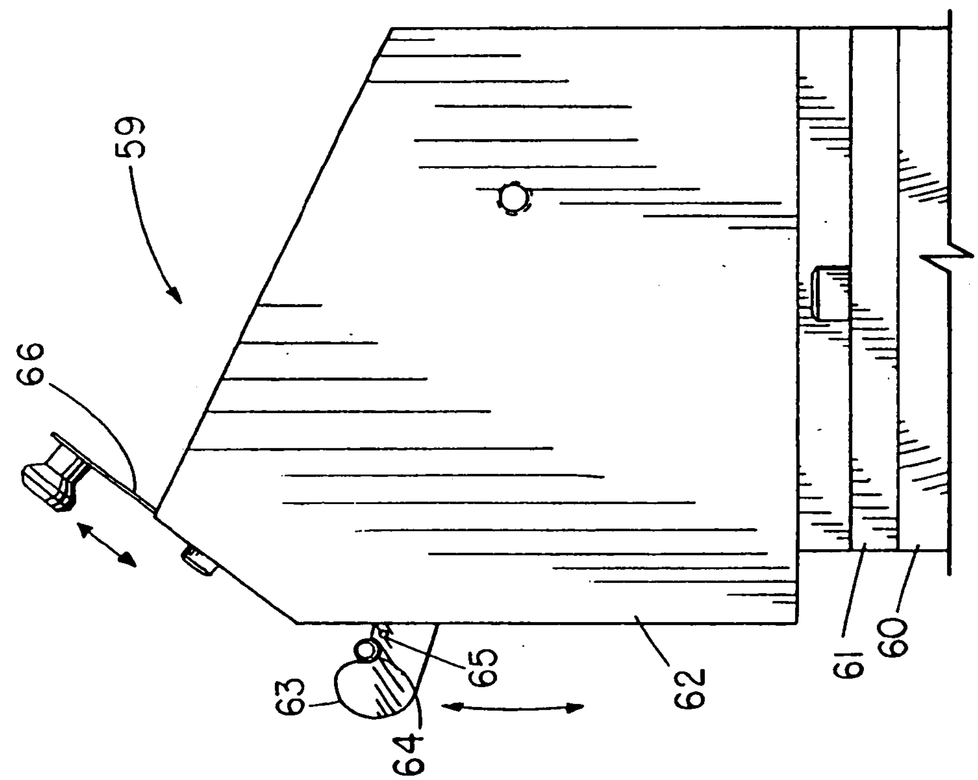

FIG. 6

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EUROPEAN SEARCH REPORT

Application Number
EP 94 30 1092

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.5)
X	US-A-4 516 972 (SAMSON) * the whole document *	1-5,8-10	A61M25/00
A	EP-A-0 144 629 (TERUMO KABUSHIKI KAISHA) * page 5, line 18 - page 6, line 28; figures 1,2 *	1-5	
A	US-A-3 879 516 (WOLVEK) * abstract; figure 2 *	1-4	
P,A	EP-A-0 530 970 (COOK) * the whole document *	1-6,8-10	

TECHNICAL FIELDS SEARCHED (Int.Cl.5)

A61M

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	4 July 1994	Kousouretas, I

CATEGORY OF CITED DOCUMENTS

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